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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/909,837	07/20/2001	Joseph A. Monforte	14-020510US	8812

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EXAMINER

MORAN, MARJORIE A

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 01/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/909,837

Applicant(s)

MONFORTE, JOSEPH A.

Examiner

Marjorie A. Moran

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– The MAILING DATE of this communication appears on the cover sheet with the correspondence address –

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 October 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-35 and 37-39 is/are pending in the application.
- 4a) Of the above claim(s) 6,24-29 and 37-39 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5,7-23 and 30-35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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Election/Restrictions

Claims 6 and 24-29 are again withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected Invention or species, there being no allowable generic or linking claim. Election was made **without** traverse in the response filed 10/16/03.

Newly submitted claims 37-39 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: claims 37-39 are directed to nonelected species. Original claim 9 limited a set of compounds to drug compositions. Original claim 14 has been amended to recite therapeutics or therapeutic candidates. As therapeutics or therapeutic candidates are generally considered by those skilled in the art to comprise drug compositions, claim 14 does not recite new matter and is directed to an originally elected species of composition. None of the original claims recited research chemicals, synthetic compositions, or herbal compositions, as recited in new claims 37-39. As the compositions of the new claims are not necessarily a drug composition nor a therapeutic composition, nor are they limited to have drug or therapeutic properties, claims 37-39 are not directed to elected species of compositions, as recited in the originally elected claims.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 37-39 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Applicant is reminded that upon a finding of allowability of a generic claim, species claims which depend from that generic claim will be considered.

An action on the merits of elected claims 1-5, 7-23 and 30-35, as they read on the elected species, follows.

Specification

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. See e.g. page 14. The examiner appreciates applicant's thorough review of the specification and amendments thereto in an attempt to overcome this objection. Unfortunately, page 14 still recites URL's, therefore the objection is maintained. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Claim Rejections - 35 USC § 112

In view of the definition set forth by WO 01/71023 (incorporated by reference into the instant specification) for a target-specific modified cell line, wherein the cell line is modified/mutated to be responsive to a particular target/stimulus (e.g. compound or composition) or to display a modified or differential response (versus an unmodified cell line) to a stimulus/target, the rejection of claim 16 is hereby withdrawn. In response to the amendment filed 10/26/04, all other rejections of claims made under 35 USC 112, 2nd paragraph are also hereby withdrawn.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-5, 7-23 and 30-35 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the

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art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This is a LACK OF ENABLEMENT rejection.

The factors to be considered in determining what constitutes undue experimentation were affirmed by the court in *In re Wands* (8 USPQ2d 1400 (CAFC 1986)). These factors are the quantity of experimentation; the amount of direction or guidance presented in the specification; the presence or absence of working examples; the nature of the invention; the state of the prior art; the level of skill of those in the art; predictability or unpredictability of the art; and the breadth of the claims.

A method of identifying a new composition with a desired activity comprising providing compositions and cell lines wherein BOTH have the same activities is not enabled. Claim 1 does not limit a "first demonstrated activity" nor a "second desired activity" to any particular activities, but does limit a first composition to comprise both activities, then in line 7 also limits a cell line to differ from a parent cell line in either "the first demonstrated activity or the second desired activity." This language thus limits both compositions and cell lines to comprise the SAME activities. The penultimate step of claim 1 recites comparing genetic profile responses to the first and second activities of each member composition to identify a particular pattern in a second set of composition. It is noted that a cellular/genetic response is compared to, not correlated with, the activities of a composition, thus confirming that the cellular activity/response is intended to be the same as the activity of a composition. Original claims 9 and 14 limit the compositions to be drug or therapeutic compositions. Original claims 10-11 limit the compositions to have antiproliferative or antineoplastic activities. None of the original claims specifically limited cell line activity.

The instant specification repeats the language of claim 1 on pages 1-2, thus providing literal support for the claim. However, the specification also discloses on page 2, lines 25-29 that a modified cell line may differ from its parent in the activity or concentration of a selected protein or nucleic acid *in response to* the addition of one or more agents. Page 2, lines 30-35 further discloses that a set of compounds maybe

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those identified for *treating* a first demonstrated activity. Page 6 discloses in lines 14-18 that it is possible to correlate a set of responses (of a cell line) with a desired activity, thereby allowing screening for compositions which produce a desired response profile. Page 6 further discloses that the compositions which have one or more desired activities are those which evoke a preferred pattern of genetic and cellular responses in cells. Page 17 discloses that during generation of genetic response profiles, cells are treated with a compositions and a variety of cellular processes (e.g. activities) may be monitored. Again, these activities are measured in *response* to the composition. The specification sets forth presumptive examples of screening on pages 25-26, but nowhere discloses compositions and cell lines which comprise the same activities. Thus, the overall disclosure of the specification is directed to compositions comprising particular activities, and to cell lines comprising particular *responses* to those activities, OR to compositions which evoke particular activities in cell lines (e.g. the cell activity is delay of transcription wherein the "activity" of the composition is inhibition of transcriptional elements). The specification does NOT disclose, anywhere, cell lines and compositions with identical activities.

The state of the prior art is such that a method of identifying compositions with multiple activities, which invoke specific responses in cells, is known (see VAN WOUDE et al. (5,645,988), as set forth in the previous office action. The prior art of VAN WOUDE does NOT teach that the cellular response is the same as that of the compositions, but teaches that the cellular responses are invoked by properties/activities of the compositions, wherein the compositions are specifically formulated to comprise the desired activities.

The level of skill in the art is acknowledged to be high. Despite this, and due to the lack of teaching in either the prior art or specification for a method of identifying

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composition with a desired activity wherein both compositions and cell lines treated with the compositions comprise the same activities, it would require undue experimentation by one skilled in the art to perform the claimed method.

Claim Rejections - 35 USC § 103

In view of the enablement rejection newly set forth above, the rejection under 35 USC 103 is hereby withdrawn. Applicant's arguments filed 7/6/04 are moot in view of this withdrawal.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marjorie A. Moran whose telephone number is (571) 272-0720. The examiner can normally be reached on Mon. to Wed, 7:30-4; Thurs 7:30-6; Fri 7-1 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571)272-0722. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Marjorie A. Moran
Primary Examiner
Art Unit 1631

Marjorie A. Moran
1/10/05